

EXHIBIT 8

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

1

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MINNESOTA

3 -----

4 In Re:

5 Bair Hugger Forced Air Warming

6 Products Liability Litigation

7

8 This Document Relates To:

9 All Actions MDL No. 15-2666 (JNE/FLM)

10 -----

11
12 DEPOSITION OF KARL D. ZGODA

13 VOLUME I, PAGES 1 - 238

14 FEBRUARY 24, 2017

15

16

17 (The following is the deposition of KARL D.

18 ZGODA, taken pursuant to Notice of Taking Deposition,

19 via videotape, at the offices of Ciresi Conlin

20 L.L.P., 225 South 6th Street, Suite 4600, in the City

21 of Minneapolis, State of Minnesota, commencing at

22 approximately 9:08 o'clock a.m., February 24, 2017.)

23

24

25

STIREWALT & ASSOCIATES
1-800-553-1953 info@stirewalt.com

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

1	279	Cobra Logic Meeting 5/24/00,	3
		3MBH00025543	57
2	280	email, Zgoda to Hanging Cobra's,	58
3	281	June 07, 2000, 3MBH00497304	
		Filter - Test Report, 3MBH00022367	65
4	282	to 2370	
		PowerPoint, Bair Hugger Therapy,	75
5	283	Model 750 Technical/Service	
		Training, Aug. 27-28, 2003,	
6	284	3MBH00017229 to 7257	85
		email, Zgoda to Lastovich,	
7	285	7/27/2008, 3MBH00026490	87
		email string, Lastovich to Zgoda,	
8	286	7/29/2008, 3MBH00026492	89
		email string, Zgoda to list,	
9	287	8/4/2008, 3MBH00026515 to 6516	95
		email string, Collins to list,	
10	288	12/19/2008, 3MBH00026708 to 6709	103
		email string, Eickhoff to list,	
11	289	1/16/2009, 3MBH00026724 to 6725	108
		Arizant Research and Development	
12	290	TEST REPORT, 3MBH00018311 to 8313	141
		email, Zgoda to Barrows/Hansen,	
13	291	7/31/2008, 3MBH00026496	146
		email string, Poppen to list,	
14	292	1/27/2009, 3MBH01807381	156
		PowerPoint, Ducky/Phase 1, Final	
15	293	Concepts, May 20, 2009,	166
		3MBH00022625 to 2662	
16	294	email, Card to Woodwick-Sides/Gary	169
		Maharaj, July 1, 2009, 3MBH00024947	
17	295	email string, Lastovich to Zgoda,	172
		8/12/2008, 3MBH00026595 to 6596	
18	296	email string, Hansen to Lastovich,	175
		11/24/2008, 3MBH00024569	
19	297	email string, Scott to list,	182
		10/2/2009, 3MBH00024682	
20	298	email string, Parthasarathy to	2398
		Oster, 8/26/2013, 3MBH00542396 to	
21	299	2398	188
		email string, Maharaj to Mark J,	
22		10/07/2013, 3MBH00126140 to 6142	198
		email, Hulse Stevens to list,	
23		8/24/2013, 3MBH00000826	201
		untitled, 3MBH01617179	
24			
25			

STIREWALT & ASSOCIATES
1-800-553-1953 info@stirewalt.com

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

2

1 APPEARANCES:

2 On Behalf of the Plaintiffs:

3 Mark D. Bankston

4 Kyle W. Farrar

5 William R. Ogden

6 KASTER, LYNCH, FARRAR & BALL, LLP

7 1010 Lamar

8 Suite 1600

9 Houston, Texas 77002

10 Noah Lauricella

11 GOLDENBERG LAW

12 800 LaSalle Avenue

13 Suite 2150

14 Minneapolis, Minnesota 55402

15 On Behalf of the Defendants:

16 Peter J. Goss

17 BLACKWELL BURKE P.A.

18 432 South Seventh Street

19 Suite 2500

20 Minneapolis, Minnesota 55415

21 On Behalf of the Deponent:

22 William A. Brewer III

23 Dale O. Fresch

24 BREWER ATTORNEYS & COUNSELORS

25 1717 Main Street

Suite 5900

Dallas, Texas 75201

ALSO PRESENT:

Jason L. Przymus, Videographer

26	EXAMINATION INDEX	
27	EXAMINED BY	PAGE
28	Karl D. Zgoda	Mr. Bankston
29		4

30	EXHIBIT	DESCRIPTION	PAGE
31	277	Memo, Zgoda to Lastovich, 3/15/99,	49
32		3MBH01735994	
33	278	Cobra Filtration Meeting 5/23/00,	54
34		3MBH00025527	

STIREWALT & ASSOCIATES
1-800-553-1953 info@stirewalt.com

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

4

09:08:25 1 PROCEEDINGS

09:08:25 2 (Witness sworn.)

3 KARL D. ZGODA,

4 Called as a witness, being first

5 duly sworn, was examined and

6 testified as follows:

7 EXAMINATION

8 BY MR. BANKSTON:

09:08:39 9 Q. All right, sir. Can you state the name for

09:08:41 10 the record?

09:08:41 11 A. Karl Zgoda.

09:08:42 12 Q. All right. Mr. Zgoda, you understand we're

09:08:43 13 here today to talk about a medical device made by 3M

09:08:46 14 known as the Bair Hugger; correct?

09:08:47 15 A. Correct.

09:08:48 16 Q. Okay. You've given a couple depositions

09:08:50 17 before regarding the Bair Hugger.

09:08:52 18 A. Correct.

09:08:52 19 Q. Okay. This -- I believe this will be your

09:08:54 20 third deposition?

09:08:54 21 A. Yes.

09:08:55 22 Q. I'm going to go ahead and assume, then,

09:08:56 23 after going over the ground rules in those depositions and

09:08:59 24 talking to your lawyers, nothing's unfamiliar about

09:09:02 25 what's going on today. You understand why you're here

STIREWALT & ASSOCIATES
1-800-553-1953 info@stirewalt.com

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

37

09:38:45 1 A. They are a firm that's representing me, yes.
 09:38:47 2 Q. Okay. So that's your lawyer. You
 09:38:49 3 understand that means you have a relationship with
 09:38:49 4 them. You have --
 09:38:51 5 A. If you want --
 09:38:52 6 Q. Okay.
 09:38:53 7 A. If you want to make that connection, sure.
 09:38:55 8 Q. So you're not like a person off the street
 09:38:56 9 asking for documents, you're in a collaborative
 09:38:59 10 relationship with these folks; right?
 09:39:02 11 MR. GOSS: Object to form.
 09:39:07 12 A. I'd say that's probably an accurate
 09:39:10 13 statement.
 09:39:11 14 Q. Right.
 09:39:11 15 They're paying you money for you to help
 09:39:13 16 them defend the case.
 09:39:16 17 MR. GOSS: Object to form.
 09:39:16 18 MR. BREWER: Objection, assumes facts not
 09:39:18 19 in evidence.
 09:39:19 20 A. I would --
 09:39:20 21 MR. BREWER: I think it misstates -- Well
 09:39:21 22 anyway. Objection to form.
 09:39:23 23 A. I would say that they have compensated me
 09:39:25 24 for my time in preparation for this case.
 09:39:31 25 Q. And you're providing a consulting service to
 STIREWALT & ASSOCIATES
 1-800-553-1953 info@stirewalt.com

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

38

09:39:32 1 them.
 09:39:34 2 MR. GOSS: Object to form.
 09:39:35 3 MR. BREWER: Objection, assumes facts not
 09:39:36 4 in evidence.
 09:39:36 5 A. Yeah, I don't know if I'd call it a
 09:39:38 6 consulting service, but I have met with them and went
 09:39:42 7 through documents and answered questions related to
 09:39:45 8 the timing and development of the 750.
 09:39:47 9 Q. Right. That's the nature of your
 09:39:49 10 consulting, right, that you're reviewing technical
 09:39:51 11 documents and sharing information with them?
 09:39:53 12 MR. BREWER: Object to the form. I think
 09:39:54 13 it misstates the testimony.
 09:39:56 14 Q. Right?
 09:39:56 15 A. I don't have any consulting agreement, and
 09:39:57 16 so I'm not sure if "consulting" is the proper term.
 09:40:01 17 Q. Any more; right? You've had a consulting
 09:40:03 18 agreement for this litigation, for these Bair Hugger
 09:40:06 19 cases.
 09:40:06 20 A. In the previous two depositions, yes.
 09:40:09 21 Q. Okay. So you've been doing consulting, you
 09:40:12 22 -- that consulting has included reviewing technical
 09:40:14 23 documents and sharing information with the defense.
 09:40:18 24 A. In previous depositions, yes.
 09:40:20 25 Q. Okay. No longer discussing technical
 STIREWALT & ASSOCIATES
 1-800-553-1953 info@stirewalt.com

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

39

09:40:23 1 documents or sharing information with them?
 09:40:25 2 A. No. We -- We discussed documents, but I
 09:40:27 3 didn't have a formal consulting agreement.
 09:40:30 4 Q. Oh, I see. So the difference now is just
 09:40:32 5 there's nothing on paper.
 09:40:34 6 MR. BREWER: Objection, --
 09:40:34 7 MR. GOSS: Object to form.
 09:40:35 8 MR. BREWER: -- improper hypothetical.
 09:40:39 9 A. Yeah, I'm not sure I agree with that
 09:40:42 10 characterization, but there is no signed document for
 09:40:44 11 a legal consulting agreement.
 09:40:47 12 Q. Okay. Let's jump back to where we kind of
 09:40:49 13 went off onto a side road there.
 09:40:51 14 A. Okay.
 09:40:52 15 Q. Where we had left off was that you were not
 09:40:54 16 personally aware of any testing that had been done
 09:40:56 17 with respect to the effect of the Model 750 on the
 09:40:58 18 operating room airflow during the development of that
 09:41:00 19 product.
 09:41:00 20 Do you remember that?
 09:41:01 21 A. Correct.
 09:41:02 22 Q. Okay. And in fact not just -- when it comes
 09:41:04 23 down to it, not just testing, but you'll agree with me
 09:41:07 24 that during the development of the Model 750, you
 09:41:11 25 didn't have any kind of discussions at all with
 STIREWALT & ASSOCIATES
 1-800-553-1953 info@stirewalt.com

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

40

09:41:14 1 respect to whether it would have an effect on the
 09:41:16 2 operating room airflow.
 09:41:17 3 MR. GOSS: Object to form.
 09:41:20 4 A. I don't personally recall any discussions
 09:41:23 5 that I had with anyone related to that -- to the
 09:41:26 6 impact it would have on the airflow in the OR.
 09:41:31 7 Q. And that means you, as project lead, in
 09:41:33 8 discussions with your engineers; correct?
 09:41:38 9 A. Engineers and other team members. But I
 09:41:40 10 guess the point I'm trying to make is there may have
 09:41:42 11 been discussion between other individual team members
 09:41:44 12 that I wasn't present or participating in, so I can't
 09:41:47 13 exclude that.
 09:41:48 14 Q. Sure.
 09:41:49 15 And this would include you've never had any
 09:41:51 16 of kind of those discussions with anybody in the
 09:41:53 17 clinical department; correct?
 09:41:55 18 A. I do not recall any discussions, no.
 09:41:57 19 Q. You've never had those kind of discussions
 09:41:59 20 with anybody in upper management; correct?
 09:42:03 21 A. Correct. I don't recall any discussions
 09:42:04 22 like that.
 09:42:05 23 Q. Okay. Now flow of air in the operating
 09:42:07 24 room, airborne contamination, these are important
 09:42:09 25 issues; right?
 STIREWALT & ASSOCIATES
 1-800-553-1953 info@stirewalt.com

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

41

09:42:15 1 **A.** I'm not a surgeon and I'm not an OR expert,
 09:42:17 2 but yes, I would agree with that.
 09:42:19 3 **Q.** Well you are the project lead of a medical
 09:42:21 4 device that's going to be placed in an operating room
 09:42:23 5 with thousands and thousands of patients. You think
 09:42:26 6 it's important that you should understand, right, that
 09:42:28 7 airborne contamination is an issue to be taken
 09:42:30 8 seriously. Am I -- Do you agree with that?
 09:42:33 9 **MR. GOSS:** Object to form.
 09:42:34 10 **A.** I would think that it's important that the
 09:42:36 11 company understand that.
 09:42:38 12 **Q.** But not you as the project lead.
 09:42:43 13 **A.** Not necessarily explicitly me, no.
 09:42:48 14 **Q.** Well again, you're the one who has to make
 09:42:50 15 sure the product is safe and that the right
 09:42:51 16 verification testing has been done in doing that.
 09:42:55 17 **A.** Making sure that the -- the verification
 09:42:58 18 testing that was identified is done properly.
 09:43:00 19 **Q.** Okay. It seems to me, then, that the main
 09:43:07 20 job of the project lead is basically to just check
 09:43:09 21 that other people did their job?
 09:43:14 22 **A.** I think that's an oversimplification, but
 09:43:16 23 you're basically the person that's orchestrating the
 09:43:19 24 project and making sure that all the tasks that are
 09:43:21 25 identified in the product development system are done

STIREWALT & ASSOCIATES

1-800-553-1953 info@stirewalt.com

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

42

09:43:25 1 satisfactorily.
 09:43:27 2 **Q.** Now when we talk about flow of air in the
 09:43:29 3 operating room, airborne contamination, --
 09:43:31 4 **A.** Umm-hmm.
 09:43:32 5 **Q.** -- that's an issue the company knew could be
 09:43:34 6 a potential hazard if the design of the device didn't
 09:43:37 7 account for it.
 09:43:38 8 **MR. BREWER:** Objection, foundation.
 09:43:39 9 **MR. GOSS:** Same objection.
 09:43:41 10 **A.** I'm sorry. Can you repeat it again?
 09:43:45 11 **Q.** Sure.
 09:43:46 12 Flow of air in the operating room, airborne
 09:43:47 13 contamination, that's an issue the company knew could
 09:43:51 14 be a potential hazard if the design of the device did
 09:43:54 15 not account for it.
 09:43:55 16 **MR. BREWER:** Objection, --
 09:43:56 17 **MR. GOSS:** Same objection.
 09:43:57 18 **MR. BREWER:** -- foundation.
 09:43:58 19 **A.** I would say some segments of the company
 09:44:00 20 would know that, yes.
 09:44:02 21 **Q.** In fact if we look -- Exhibit 47, right,
 09:44:05 22 where it talks airborne contaminants can be blown
 09:44:08 23 around the room and it lists two ways to mitigate it,
 09:44:12 24 and then they had their published testing on units
 09:44:14 25 with the same filter and same air output when they

STIREWALT & ASSOCIATES

1-800-553-1953 info@stirewalt.com

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

43

09:44:17 1 validated the device.
 09:44:18 2 **MR. GOSS:** Object to form.
 09:44:19 3 **Q.** In validating the 750, what testing did you
 09:44:23 4 rely on?
 09:44:24 5 **A.** As far as validating the device?
 09:44:26 6 **Q.** As far as this, prevention of airborne
 09:44:28 7 contamination. What testing did you rely on to assure
 09:44:31 8 us that the unit is safe?
 09:44:32 9 **MR. GOSS:** Object to form.
 09:44:33 10 **MR. BREWER:** Objection, assumes facts.
 09:44:36 11 **A.** I would say --
 09:44:42 12 I'm not aware of any verification testing
 09:44:45 13 that was done internal to the company to verify this,
 09:44:50 14 but as far as clinical tests or studies that might
 09:44:53 15 have been done after launch of the product, I'm not
 09:44:57 16 aware of any of that having been done.
 09:45:00 17 **Q.** Sure. Well let's stick with the
 09:45:02 18 development, because as I remember you telling me, if
 09:45:05 19 something changes that could impact the safety
 09:45:08 20 assurances made in the federal government filings,
 09:45:10 21 that needs to be validated and verified.
 09:45:13 22 Remember telling me that?
 09:45:16 23 **MR. GOSS:** Object to form.
 09:45:21 24 **A.** I don't know what the filing for the 750
 09:45:24 25 said. I a --

STIREWALT & ASSOCIATES

1-800-553-1953 info@stirewalt.com

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

44

09:45:25 1 **Q.** Sure. Let me just back you up.
 09:45:27 2 **A.** Okay.
 09:45:28 3 **Q.** All I asked you is do you remember telling
 09:45:29 4 me that if something changes that could impact the
 09:45:32 5 safety assurances in the federal filing it needed to
 09:45:34 6 be verified?
 09:45:36 7 **A.** Yes. I recall saying that.
 09:45:37 8 **Q.** Okay. And you will agree with me that
 09:45:39 9 something has changed. The air output in this unit
 09:45:41 10 has changed.
 09:45:43 11 **A.** Yes, the air output has changed.
 09:45:45 12 **Q.** And the air output is something that is
 09:45:46 13 specifically discussed in the safety claims for the
 09:45:48 14 unit, the 505.
 09:45:51 15 **A.** Correct.
 09:45:51 16 **Q.** So it would require verification testing
 09:45:53 17 that was not performed; correct?
 09:45:55 18 **MR. GOSS:** Object to form.
 09:45:58 19 **A.** Verification testing was performed to verify
 09:46:02 20 the increased airflow of the device and the heat
 09:46:05 21 transfer rate, but that -- but not anything dealing
 09:46:08 22 with OR airflow.
 09:46:10 23 **Q.** Or safety.
 09:46:12 24 **MR. GOSS:** Object to form.
 09:46:13 25 **A.** Well no. I mean there's plenty of safety

STIREWALT & ASSOCIATES

1-800-553-1953 info@stirewalt.com

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

205

14:03:27 1 You can now acknowledge that that change
 14:03:29 2 that you made in airflow may be a cause of the
 14:03:32 3 increased particulate counts being observed in
 14:03:34 4 studies.
 14:03:35 5 MR. GOSS: Object to form.
 14:03:36 6 MR. BREWER: Objection, foundation.
 14:03:39 7 A. And I don't think I really have the
 14:03:42 8 background in those studies or the testing that was
 14:03:43 9 done and how they did it, and so I think any opinion I
 14:03:47 10 would interject is not of great value.
 14:03:51 11 Q. If you had to do it over again, if we could
 14:03:55 12 turn back the hands of time and go back to developing
 14:03:58 13 the 750 again, you'd want to make sure these tests
 14:04:00 14 were done; wouldn't you?
 14:04:04 15 A. A lot of things are obvious in hindsight,
 14:04:07 16 but given where we're sitting today, yes, it probably
 14:04:10 17 would have been prudent to do them. But they were not
 14:04:14 18 on my radar to do, so.
 14:04:16 19 Q. As the person who was responsible for the
 14:04:18 20 safety and to make sure all the val -- verification
 14:04:20 21 testing had been done, that hadn't --
 14:04:22 22 A. Once again --
 14:04:22 23 Q. I'm sorry. I gotta finish my question
 14:04:25 24 before. She can only take down one of us at a time.
 14:04:27 25 As the person who was being responsible for
 STIREWALT & ASSOCIATES
 1-800-553-1953 info@stirewalt.com

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

206

14:04:29 1 the safety and verification testing, you could only
 14:04:31 2 verify what had been put on your list to verify;
 14:04:34 3 correct?
 14:04:34 4 A. Yes. I'm sorry.
 14:04:35 5 I would say that was accurate. It was my
 14:04:37 6 responsibility to make sure that all the verification
 14:04:39 7 testing that was identified by the team was executed
 14:04:42 8 satisfactorily.
 14:04:42 9 Q. And if that safety issue wasn't put on your
 14:04:45 10 radar by somebody, it wasn't going to get checked.
 14:04:50 11 A. I would say that's likely, yes.
 14:04:53 12 Q. Who should have put it on the list?
 14:04:59 13 A. That would just be conjecture on my part.
 14:05:05 14 I'm not sure I could say who would be responsible for
 14:05:07 15 that.
 14:05:09 16 Q. I've sat in this room many hours and I've
 14:05:12 17 talked to many of your colleagues, and I have been
 14:05:14 18 looking for a long time for the person who can tell me
 14:05:17 19 who's responsible for getting all of the testing done
 14:05:19 20 on the 750, making sure that the right things were
 14:05:23 21 tested. And if there is anything you can tell me
 14:05:25 22 today about who that person might have been, is there
 14:05:28 23 any information that you can have that can lead me to
 14:05:31 24 that right person?
 14:05:32 25 MR. GOSS: Object to the preamble.
 STIREWALT & ASSOCIATES
 1-800-553-1953 info@stirewalt.com

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

207

14:05:34 1 MR. BANKSTON: I'll allow it.
 14:05:35 2 MR. BREWER: Objection, foundation.
 14:05:37 3 A. I'm sorry. Can you either rephrase it or
 14:05:41 4 repeat it based on their objections?
 14:05:42 5 Q. Yeah.
 14:05:43 6 I've been hoping for a long time to find out
 14:05:45 7 who that person is. You know what I mean when I say
 14:05:47 8 "who that person is."
 14:05:49 9 A. Yep.
 14:05:49 10 Q. Is there anything you can tell that tells me
 14:05:51 11 who the person is who should have put that information
 14:05:53 12 on the list or should have come up with the things
 14:05:55 13 that needed to be tested on the Bair Hugger?
 14:05:58 14 A. I'm not sure who that individual would be,
 14:06:01 15 and once again, it's a -- you know, it's a team
 14:06:04 16 effort, every department is represented. As part of
 14:06:07 17 the effort we identified whatever testing needed to be
 14:06:10 18 done to verify and validate the device, and we did
 14:06:12 19 that.
 14:06:13 20 Now whether you say it's, you know,
 14:06:15 21 regulatory because they knew what was filed with the
 14:06:18 22 FDA or, you know, clinical because of the
 14:06:21 23 applications. I'm not equipped to say it was one
 14:06:24 24 person.
 14:06:28 25 Q. Sometime after you left 3M someone contacted
 STIREWALT & ASSOCIATES
 1-800-553-1953 info@stirewalt.com

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

208

14:06:32 1 you to let you know about the existence of a lawsuit
 14:06:36 2 involving the Bair Hugger; right?
 14:06:38 3 A. I don't know about the timing of that. I
 14:06:42 4 don't know if I knew about the existence of the
 14:06:44 5 lawsuit before I left or not.
 14:06:47 6 Q. Okay. I see what you're saying. Okay.
 14:06:49 7 But somewhere in the recent timeframe you
 14:06:53 8 were informed that there was a lawsuit with the Bair
 14:06:55 9 Hugger.
 14:06:55 10 A. Yes.
 14:06:56 11 Q. Who was that who told you; do you remember?
 14:06:59 12 A. I don't recall. I think it was somebody
 14:07:01 13 internal to 3M and not out of the blue, but I can't
 14:07:06 14 say definitively who told me.
 14:07:07 15 Q. Okay. And at that time you negotiated an
 14:07:09 16 agreement with a law firm in which they would pay to
 14:07:12 17 act you as their consultant.
 14:07:15 18 A. I had an LCA with --
 14:07:18 19 So when I left the company 3M made the law
 14:07:24 20 firm available to me as part of the litigation
 14:07:28 21 arrangement.
 14:07:30 22 Q. No. What I'm asking is you negotiated an
 14:07:34 23 agreement with that law firm in which that law firm
 14:07:36 24 would pay you money to consult with them on the
 14:07:38 25 lawsuit.
 STIREWALT & ASSOCIATES
 1-800-553-1953 info@stirewalt.com